



# UNITED STATES PATENT AND TRADEMARK OFFICE

TC

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1459  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/549,858	04/14/2000	James McShane	109536.132	9181

7590  
01/30/2004  
Hollie L. Baker  
Hale and Dorr LLP  
60 State Street  
Boston, MA 02109

EXAMINER

JONES, DWAYNE C

ART UNIT PAPER NUMBER

1614

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/549,858

Applicant(s)

MC SHANE ET AL.

Examiner

Dwayne C Jones

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on the remarks of 22DEC2003 and 20MAY2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other:

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-23 are pending.
2. Claims 1-23 are rejected.

### ***Response to Arguments***

3. Applicants' arguments filed May 20, 2003 have been fully considered but they are not persuasive. Applicants present the following arguments. First, applicants allege that the prior art reference of Oishi et al. does not teach that the amino acid of glycine does not provide stabilization for the benzimidazole compounds. Second, applicants argue that Takechi et al. only teach of using amides to stabilize benzimidazoles rather than the instantly claimed amino acid of glycine. In addition, applicants allege that sugars are the preferred form regulators of Takechi et al.
4. First, applicants allege that the prior art reference of Oishi et al. does not teach that the amino acid of glycine does not provide stabilization for the benzimidazole compounds. Oishi et al. do teach of a stabilized formulation that is comprised of benzimidazole and glycine. In addition, Oishi et al. do in fact teach of methods and provide motivation to stabilize benzimidazole compounds. The compositions of Oishi et al. are also comprised of the component of glycine, (see Table 1 and Example 7). The instant method claims, and composition claims for that matter, only required the presence of benzimidazole and the amino acid of glycine. It is also indicated that the presently claimed invention is written with open-claim language. For instance,

applicants recite the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310. For these above-stated reasons, the instant invention is rendered obvious in view of Oishi et al.

5. Second, applicants argue that Takechi et al. only teach of using amides to stabilize benzimidazoles rather than the instantly claimed amino acid of glycine. The instant claims as currently written are only directed to (a) composition claims that are comprised of benzimidazole and glycine and (b) methods of stabilizing an anti-ulcerative formulation with a composition that is comprised of benzimidazole and the amino acid of glycine. Given these requirements the prior art reference of Takechi et al. do in fact teach of a stabilized injectable composition that is comprised of benzimidazole and glycine as well as stabilized methods of an injectable composition that is comprised of benzimidazole and glycine. Furthermore, the instant claims are written in open-claim language with the use of the word comprising. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

6. Applicants next allege that sugars are the preferred form regulators of Takechi et al. Takechi et al. render the instant claims obvious because Takechi et al. teach of the very same components that are claimed by applicants, namely benzimidazole and glycine. Takechi et al. may list preferred regulators as sugars. However, the fact

Art Unit: 1614

remains that Takechi et al. clearly teach of a composition and methods of stabilized compositions that are comprised of benzimidazole and glycine. Accordingly, the instant invention is rendered obvious of Takechi et al.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. The rejection of claims 1-23 under 35 U.S.C. 103(a) as being unpatentable over Oishi et al. of H5-194225. Oishi et al. teach of stabilized anti-ulcer preparations, which contain an amino acid, namely glycine, and a benzimidazole compound, (see claims 1,2 and 4). The claims differ from the reference by reciting a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the benzimidazole genus as taught by Oishi et al., including those of the claims, because an ordinary artisan would

have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

10. The rejection of claims 1-23 under 35 U.S.C. 103(a) as being unpatentable over Takechi et al. of U.S. Patent No. 5,536,735. Takechi et al. teach of a stable injectable preparation, which has anti-ulcer activity and that contains an amino acid, namely glycine, and a benzimidazole compound, (see columns 1,2,5,6 and column 8). The claims differ from the reference by reciting a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the benzimidazole genus as taught by Oishi et al., including those of the claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634 until about February 6, 2004 and then changes to (571) 272-0578. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725 until about February 6, 2004 and then changes to (571) 272-0584. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Art Unit: 1614

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.



Tech. Ctr. 1614

January 28, 2004